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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/788,906	GIROUARD ET AL.
	Examiner	Art Unit
	Jessica L. Reidel	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/28/2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7,10-38,41-148,150 and 151 is/are pending in the application.

4a) Of the above claim(s) 4-7,14-31,35-38,45-62 and 79-148 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3,10-13,32-34,41-44,63-78,150 and 151 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 February 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/07.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on September 28, 2007. Claims 8, 9, 39, 40, and 149 have been cancelled. Claims 150 and 151 are new and have been added. Claims 1-7, 10-38, 41-148, 150 and 151 are pending. Claims 4-7, 14-31, 35-38, 45-62 and 79-148 were previously withdrawn.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on September 28, 2007 has been acknowledged and is being considered by the Examiner. Applicant should note that the large number of references in the attached IDS (both previously and newly submitted) have been considered by the Examiner in the same manner as other documents in Office search files are considered by the Examiner while conducting a search of the prior art in a proper field of search. See MPEP § 609.05(b). Applicant is respectfully requested to point out any particular references in the IDS which they believe may be of particular relevance (i.e. material to patentability) of the instant claimed invention in response to this Office Action in an effort to expedite prosecution.

Claim Objections.

3. Claim 63 is objected to because of the following informalities: the claim identifier refers to this claim as being "Withdrawn – Currently Amended". The Examiner believes this to be in error and respectfully requests that the claim identifier be changed to reflect the current status of the claim. Claim 63 was not withdrawn in response to the Requirement for Restriction/Election of September 23, 2005 as noted in previous Office Actions. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. ***Claims 1-3, 13, 32-34, 44, 63, 64, 67-73 and 150-151 are rejected under 35 U.S.C. 102(a) and under 35 U.S.C. 102(e) as being anticipated by Padua et al. (U.S. 2003/0204206) (herein Padua).*** As to Claims 1 and 13, Padua expressly discloses an implantable medical device system 22, such as a pacemaker or pacemaker/cardioverter/defibrillator, for controlling and regulating production of therapeutic products (see Padua Figs. 11 and 12) comprising one or more sensors (i.e. intracardiac electrogram sensing electrodes, a subcutaneous electrode array, blood gas sensors, pH sensors, blood flow sensors etc.) for sensing physiological signals indicative of predetermined cardiac conditions (i.e. ischemia or reduced blood flow). Padua specifies that a sensing element of the system 22, read as an event detector is adapted to detect the predetermined cardiac condition from a sensed physiological signal and to produce one or ore conditions parameters related to the type of the predetermined condition where the conditions parameters (i.e. ST segment elevation or reduction of blood blow in the coronary sinus) are used in a closed-loop control algorithm of the system 22 (see Padua page 1, paragraph 5, page 3, paragraphs 37-40, page 11, paragraphs 162 and 164, page 12, paragraphs 170-173 and page 13, paragraphs 181-183).

Specifically, a one or more implanted electrodes of the system, read as gene regulatory signal delivery devices emit sub-threshold stimulation, read as a regulatory signal which regulates transcription from a regulatable transcriptional control element (i.e. an electrically responsive promoter (ERP)) in an expression vector (i.e. a plasmid, adenovirus vector, retrovirus vector or the

like) having the regulatable transcriptional control element operably linked to an open reading frame, the expression of which treats the predetermined cardiac condition. Padua expressly discloses that the system 22 provides for introducing into at least one cell of a patient a vector containing an electrically responsive element (ERE) operably linked to a promoter to form an electrically responsive promoter (ERP) that modulates transcription of an operably linked therapeutic product in a cell upon delivery of the regulatory signal. Padua further discloses that the genetically engineering electrically responsive promoter (ERP) is operably linked to a therapeutic gene sequence, the expression of which is controlled by the regulatory signal emitted by the gene regulatory delivery devices (i.e. the implanted electrodes) of the system 22 (see Padua page1, paragraphs 1-9, page 2, paragraphs 11-12, pages 3-6, paragraphs 59-105, pages 8-10, paragraphs 117-144, page 11, paragraphs 156-161 and page 13, paragraphs 177-180). A microprocessor or controller/timer circuit, read as a controller 92 is coupled to the one or more sensor(s) of the system 22 via sense amplifier 53 or electrogram amplifier 76 and is electrically wired to the gene regulatory signal delivery devices (i.e. the implanted electrodes) via implanted leads 24 (see Padua Figs. 11 and 12, page 1, paragraph 5, page 9, paragraphs 135-136, page 11, paragraphs 160-161, page 12, paragraphs 170-172 and page 13, paragraphs 179-180).

Padua expressly discloses that the controller 92 is adapted to quantitatively control emission of regulatory signals from the gene regulatory signal delivery devices (i.e. electrodes), the quantitative control based on the determined one or more condition parameters (i.e. ST segment elevation or reduction of blood blow in the coronary sinus) in order to closely modulate the time, frequency, and delivery amount of the therapeutic product and to closely define the locus of delivery (see Padua page 1, paragraph 5, page 5, paragraphs 84 and 88-91, page 9, paragraphs 131-136 and pages 11-13, paragraphs 156-183). Padua specifies at page 11, paragraph 159 that the controller 92

elicits temporal and spatial control of the ERP in vivo in order to evoke maximum ERP response. Padua further specifies at page 11, paragraph 164 and page 12, paragraphs 172-173 that once the event detector detects the predetermined cardiac condition, controller 92, signals the pulse generator 74 to provide an electrical stimulus or set of electrical stimulation to the ERP promoters to transcribe the therapeutic gene, the stimulation, read as the regulatory signals having predetermined timing and wave shape.

6. As to Claims 2 and 3, in addition to the arguments previously presented, the gene regulatory delivery devices (i.e. the implanted electrodes) of the system 22 disclosed by Padua further comprise an output pulse generator, read as an electromagnetic field generator 74 which emits an electromagnetic field through sub-threshold or threshold stimulation. Padua expressly discloses that the field has a predetermined frequency of about 10 to 100 Hz (see Padua page 11, paragraphs 156-158, page 12, paragraphs 172-176 and page 13, paragraph 179).

7. As to Claims 32-34 and 44, in addition to the arguments previously presented, the implantable medical device system 22 of Padua also comprises an implant radio frequency (RF) transmitter and receiver, read as a telemetry module 55 to receive external commands from either a physician or the patient. Padua expressly discloses that telemetry module 55 contains a means of receiving and transmitting RF commands and information between the implantable medical device system 22 and the patient or physician in a manner that allows regulating the output of pulse generator, read as electromagnetic field generator 74. Specifically, the telemetry module programs the implantable medical system 22 such that controller 92 quantitatively controls emission of the regulatory signals, as previously discussed, and based on the received external commands from physician and/or patient. Padua further discloses that an external system includes an external programmer which transmits the physician's commands (i.e. RF encoded signals for programming)

to the implantable medical system 22 via an external telemetry module of the programmer (see Padua pages 11 and 12, paragraphs 162-173).

8. As to Claim 63, Padua expressly discloses that implantable pulse generators that are well known in the art may be modified to stimulate the injected/implanted/introduced ERP-cells in accordance with the teachings of the implantable medical device system 22 such as a wide variety of microprocessor based implantable pacemakers and implantable pacemaker/cardioverter/defibrillators (see Padua page 11, paragraph 166). Padua further specifies that the implantable medical device system 22 may further comprise a pacing circuit coupled to the implant controller 92 and that the controller 92 may include a pacing module adapted to control delivery of threshold stimulation (i.e. pacing pulses) in conjunction with the emission of the regulatory signal/signals (see Padua page 4, paragraphs 74-76, page 5, paragraphs 83-85 and paragraphs 88-91 and page 11, paragraphs 156-160).

9. As to Claims 67, 69 and 70, in addition to the arguments previously presented, it is inherent that the controllers of such modified implantable pacemaker/cardioverter/defibrillators (see Padua page 11, paragraph 166) would provide control of defibrillation/cardioversion circuitry in conjunction with the emission of the regulatory signal/signals. Padua expressly discloses that the implantable medical device system 22 disclosed may be incorporated into that defibrillator of Bardy (U.S. 5,314,430). Bardy discloses an atrial defibrillation lead 15 coupled to an atrial defibrillation circuit and a ventricular defibrillation lead 116 coupled to a ventricular defibrillation circuit of an implantable pacemaker/cardioverter/defibrillator (see Bardy Figs. 1-3 and column 8, lines 31-65 and column 9, lines 10-63).

10. As to Claims 64 and 68, in addition to the arguments previously presented, Padua discloses that the implantable medical device system 22 disclosed may be incorporated into the rate-responsive pacemaker of Shelton et al. (U.S. 5,312,453) which discloses delivery of pacing pulses based on at

least an external physician based commands or the system 22 may be incorporated into the implantable pacemaker/cardioverter/defibrillator of Bardy (U.S. 5,314,430) which discloses delivery of particular therapies based on external programming commands (see Padua page 11, paragraph 166).

11. As to Claim 71, Padua expressly disclose that the implantable medical device system 22 comprises a hermetically sealed can 14 to house at least the implant controller 92 and the implant telemetry module 55 (see Padua Figs. 11-12, page 11, paragraphs 162-163 and page 12, paragraph 169).

12. As to Claim 72, as previously discussed, the one or more physiological sensors of system 22 may include an intracardiac electrogram sensing circuit 76 for receiving amplified and processed signals electrogram (EGM) signals. Controller 92 is coupled to the EGM sensor circuit 76 within the hermetically sealed can 14 (see Padua Fig. 12 and page 12, paragraph 171).

13. As to Claim 73, as previously discussed, the one or more physiological sensors of system 22 may include intracardiac electrogram sensing electrodes and/or a subcutaneous electrode array and/or blood flow sensors in the coronary sinus, all of which are external to the hermetically sealed can 14 (see Padua Fig. 12 and page 13, paragraph 182).

14. As to Claim 150, in addition to the arguments previously presented, in some embodiments of Padua, the vector is not "part of an implantable device". Padua expressly discloses that the ERP constructs can be delivered directly to tissues of cells of the patient in vivo through the use of an appropriate gene delivery vector (viral or non-viral) through direct injection into the target tissue or through intravenous injection through a catheter (see Padua page 1, paragraph 5 and pages 9-10, paragraphs 131-144).

15. As to Claim 151, in addition to the arguments previously presented, the controller 92 comprises a timer circuit (see Padua Fig. 12 and page 12, paragraph 168) adapted to time a predetermined time period of delivery time during which the gene regulatory signal delivery devices (i.e. the electrodes) emit the regulatory signal/signals. Padua expressly discloses that the controller 92 of the system 22 is used to closely modulate the time, frequency and delivery amount of the therapeutic product and the locus of delivery and specifies that delivery of the therapeutic product can be controlled by the location of the electrodes and the period of electrical stimulation (see Padua page 1, paragraph 5 and page 9, paragraph 136). The regulatory signals are provided through predetermined timing and wave shape defined by the controller 92 and its timer circuit (see Padua page 12, paragraphs 172-173).

16. Claims 10-12 and 41-43 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Padua in view of Donahue et al. (U.S. 2002/0155101) (herein Donahue). As previously discussed, Padua expressly discloses that implantable pulse generators that are well known in the art may be modified to stimulate the injected/implanted/introduced ERP-cells in accordance with the teachings of the implantable medical device system 22 such as a wide variety of microprocessor based implantable pacemakers and implantable pacemaker/cardioverter/defibrillators (see Padua page 11, paragraph 166). A plurality of the implantable pacemakers and implantable pacemaker/cardioverter/defibrillators cited by Padua at page 11, paragraph 166 include event detection circuitry which comprise atrial and ventricular fibrillation detectors such as Bardy (U.S. 5,314,430).

Furthermore, Donahue teaches that it is well known in the art to use a regulatable transcriptional control element in cardiac gene therapy for treatment of any of the following: sinus

bradycardia, sinus tachycardia, atrial tachycardia, atrial fibrillation, atrial flutter, atrioventricular nodal block, atrioventricular node reentry tachycardia, atrioventricular reciprocating tachycardia, ventricular tachycardia or ventricular fibrillation (see Donahue page 7, paragraph 94). Donahue also discloses that practice of the invention is broadly compatible with one or a combination of different administration systems (see Donahue page 7, paragraph 88) for more effective and flexible anti-arrhythmic therapies by providing therapeutic methods for administering one or more therapeutic polynucleotides to the heart under conditions sufficient to modulate (increase or decrease) at least one heart electrical property. Donahue further discloses that the invention modulates heart electrical conduction, reconfigures all or part of the cardiac action potential (AP) and reduces or avoids significant disruption of normal electrical function (see Donahue page 2, paragraph 14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Padua in view of Donahue to administer the gene therapy upon detection of an atrial fibrillation or ventricular fibrillation to better the system's capabilities of eliminating a wide variety of predetermined cardiac conditions.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. ***Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Padua and/or under 35 U.S.C. 103(a) as being unpatentable over Padua in view of Thompson et al. (U.S. 5,902,324) (herein Thompson) or Kroll (U.S. 6,865,420).*** Padua discloses the claimed invention, as previously discussed, except that it is not specified that the implantable medical device system 22 further comprises a cardiac resynchronization therapy (CRT) circuit coupled to the implant controller and wherein the implant controller includes a CRT control module adapted to control delivery of CRT in conjunction with the emission of the regulatory signal. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system as taught Padua with a CRT circuit coupled to the implant controller where the implant controller includes a CRT control module adapted to control delivery of CRT in conjunction with the emission of the regulatory signal, because Applicant has not disclosed that such modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pacing circuitry, cardioversion circuitry or defibrillation capabilities as taught by Padua, because it provides suitable integration of the invention with most current implantable pulse generators of the art and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Padua. Furthermore, cardiac stimulation devices for providing CRT to post-ischemic or myocardial infarction congestive heart failure patients are conventional and well known in the art. The Examiner provides Thompson and Kroll as being but two examples of implantable medical systems which include CRT circuits coupled

to implant controllers, where the controllers include a CRT control module adapted to control delivery of CRT.

20. ***Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Padua and/or under 35 U.S.C. 103(a) as being unpatentable over Padua in view of Salo (U.S. 2003/0105493).*** Padua discloses the claimed invention, as previously discussed, but does not expressly discloses an embodiment where the implantable medical device system 22 further comprises a remodeling control (RCT) therapy circuit coupled to the implant controller and wherein the implant controller includes a RCT control module adapted to control delivery of RCT in conjunction with the emission of the regulatory signal. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system as taught by Padua with a RCT circuit coupled to the implant controller where the implant controller includes a RCT control module adapted to control delivery of RCT in conjunction with the emission of the regulatory signal, because Applicant has not disclosed that such modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pacing circuitry, cardioversion circuitry or defibrillation capabilities as taught by Padua, because it provides suitable integration of the invention with most current implantable pulse generators of the art and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Padua. Furthermore, Salo teaches that preventing or minimizing post-infarct remodeling by RCT pre-excitation of the ventricle is crucial for preventing or minimizing progressive ventricular dilation in a patient. Sala expressly discloses an RCT therapy circuit coupled to an implant controller 10, where the controller 10 includes an RCT control module adapted to control delivery of the RCT therapy (see Salo Abstract, page 1, paragraphs 5-6 and pages 2-3, paragraphs 17-20). Since Padua treats heart attack or stroke (i.e. ischemia or ischemic injury), as

previously discussed, and since Padua specifies that implantable pacemaker/cardioverter/defibrillator devices known in the art may incorporate the system 22 of the invention, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Padua in view of Salo such that it includes a remodeling control (RCT) therapy circuit coupled to the implant controller, wherein the implant controller includes a RCT control module adapted to control delivery of RCT in conjunction with the emission of the regulatory signal in order to prevent or minimize progressive ventricular dilation in a post-infarct patient.

21. ***Claims 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Padua in view of Nelson et al. (U.S. 2002/0072785).*** As to Claims 74 and 75, Padua discloses that the analog electrogram of the patient's electrical heart activity may be uploaded to the external programming device (see Padua page 12, paragraph 171) but does not expressly disclose that the electrogram is displayed. It is inherent that the programmer includes a user input to receive the programming commands of the physician, otherwise the selectivity expressly discussed by Padua for the sub-threshold stimulation parameters would not be encoded within the external command signals (see Padua pages 11-12, paragraphs 167 and 173). Padua discloses the claimed invention as discussed above except that the external system does not comprise a presentation device to present the sensed physiological signal or a user. The Examiner considers the use of a presentation device to present the sensed physiological signal to a user to clinical review, such as an external device including a display to be conventional and well known in the art with Nelson being but one example (see Nelson page 7, paragraph 58).

22. As to Claims 76-78, Padua discloses that the external system comprises an advanced patient management system including an external device wirelessly coupled to the implantable medical device system via telemetry (i.e. the external programmer), as previously discussed. Padua discloses

the claimed invention as discussed above except that it is not specified that the advanced patient management system also includes a remote device to provide access to the implantable medical device system from a distant location and a network connecting the external device and the remote device. The Examiner considers the use of a remote device with a network to be conventional and well known in the art of external programming for implantable medical devices with Nelson being but one example (see Nelson Abstract, Fig. 1, page 1, paragraph 6 and page 4, paragraphs 28-32).

Double Patenting

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. ***Claims 1-3, 10-13, 32-34, 41-44, 63-78, 150 and 151 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36, 38-78, 96-111 of copending Application No. 10/890,825 (Amended September 11, 2007) in view of Padua.*** Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. As to Claims 1 and 32 of the current application, Application No. 10/890,825 also claims an implantable medical system, comprising a sensor to sense a physiological

signal indicative of a predetermined cardiac condition, an event detector, coupled to the sensor, to detect the predetermined cardiac condition from the physiological signal, an implant telemetry module to receive an external command and an implant controller coupled to the event detector and the implant telemetry module, the implant controller including a gene or protein delivery control module adapted to produce an electrical signal to control gene or protein delivery in response to the predetermined cardiac condition and the external command. Similar analysis may be applied to the remaining dependent claims of the current application upon inspection of the conflicting and pending claims 1-36, 38-78, 96-111 of copending Application No. 10/890,825.

The co-pending application includes synonymous limitations, as discussed, except does not specify that the protein delivery be provided by a regulatable transcriptional control element (i.e. an electrically responsive promoter (ERP)) in an expression vector (i.e. a plasmid, adenovirus vector, retrovirus vector or the like) having the regulatable transcriptional control element operably linked to an open reading frame, the expression of which produces the protein. Padua, however, teaches that the use of such ERP-cells is conventional and known in the art for providing selective and regulated gene therapy in a patient (see those sections of Padua cited above in this Office Action). Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to modify the claims of co-pending Application No. 10/890,825 such that the protein production is provided by an electrically responsive promoter (ERP) in an expression vector having the ERP operably linked to an open reading frame, the expression of which produces the protein, as taught by Padua, since such a modification would provide selective and regulated gene therapy. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. ***Claims 1-3, 10-13, 32-34, 41-44, 63-78, 150 and 151 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 11/220,397.*** Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. As to Claims 1 and 32 of the current application, Application No. 11/120,397 also claims a sensing circuit to sense one or more parameters indicative of an ischemic event, an ischemia detector, coupled to the sensing circuit, to detect the ischemic event from the one or more parameters, a gene regulatory signal delivery device adapted to emit at least one gene regulatory signal that regulates transcription from a regulatable transcriptional control element within a vector and operably linked to an open reading frame and a controller coupled to the ischemia detector and the gene regulatory signal delivery device, the controller adapted to quantitatively control the emission of the regulatory signal from the gene regulatory signal delivery device. Similar analysis may be applied to the remaining dependent claims of the current application upon inspection of the conflicting and pending claims 1-31 of copending Application No. 11/120,397. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. ***Claims 1-3, 10-13, 32-34, 41-44, 63-78, 150 and 151 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 11/276,077.*** Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. As to Claims 1 and 32 of the current application, Application No. 11/276,077 also claims a sensing circuit to sense one or more parameters indicative of an event, a gene regulatory signal delivery device adapted to emit at least

one gene regulatory signal that regulates transcription from a regulatable transcriptional control element within a vector and operably linked to an open reading frame and a controller coupled to the ischemia detector and the gene regulatory signal delivery device, the controller adapted to quantitatively control the emission of the regulatory signal from the gene regulatory signal delivery device. Similar analysis may be applied to the remaining dependent claims of the current application upon inspection of the conflicting and pending claims 1-41 of copending Application No. Application No. 11/276,077. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

27. Applicant's arguments with respect to claims 1 and 32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
November 28, 2007

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
December 03, 2007